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#### Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
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(54) Title: MODIFIED RELEASE COMPOSITIONS COMPRISING TACROLIMUS

(57) Abstract: A modified release composition comprising tacrolimus releases less than 20% w/w of the active ingredient within 0.5 hours when subjected to an in vitro dissolution test using USP Paddle method and using 0.1 N HCl as dissolution medium and has increased bioavailability by effectively reducing or even avoiding the effects of CYP3A4 metabolism. The modified composition may be coated with an enteric coating; and/or may comprise a solid dispersion or a solid solution of tacrolimus in a hydrophilic or water-miscible vehicle and one or more modifying release agents; and/or may comprise a solid dispersion or a solid solution of tacrolimus in an amphiphilic or hydrophobic vehicle and optionally one or more modifying release agents.



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